

REMARKS/ARGUMENTS

Claims 1-9 were pending in the present application before the amendment as set forth above. Among them, claims 8 and 9 were withdrawn from consideration as directed to non-elected subject matters. By this amendment, as set forth above, claims 1-7 are amended, and new claim 10 is added.

In the March 26, 2007 Office Action, the Examiner rejected claims 1-7 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Furthermore, claims 1-5 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over PCT Pub. No. WO 89/09620, to Leskovar et al. (hereinafter "Leskovar"). Moreover, claims 1-7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Leskovar as applied to claims 1-5 and 7 above, and further in view of U.C. Pat. No. 6,200,754 to Housman et al. (hereinafter "Housman").

Applicant very appreciates the Examiner's careful review of the application.

In response, as set forth above, claims 1-7 have been amended, as suggested by the Examiner, to particularly point out and distinctly claim the subject matter of the invention. New claim 10 has been introduced to conform claims to the embodiments of the present invention and disclosed in the application, as originally filed.

Applicant asserts that no new matter is added.

The following remarks herein are considered to be responsive thereto.

35 U.S.C. §112 Rejections

Claims 1-7 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As set forth above, in response, claims 1-7 have been amended, according to the Examiner's suggestions, to particularly point out and distinctly claim the subject matter of the invention. Specifically, claim 1 has been amended to replace the phrase of "pharmaceutical preparation" with "pharmaceutical composition", and to correct the improper Markush form. Claims 2-4 have been amended to correct informalities. Claim 5 has been amended to

particularly point out that “the anthracyclines comprise at least one of doxorubicin, daunomycin, actinomycin D and mitoxantrone.” Claim 6 has been amended to particularly recite that “the platinum complexes comprise at least one of cis-platinum, oxaliplatinum and carboplatinum.” And claim 7 has been amended to clearly claim a process of producing the pharmaceutical composition of amended claim 1.

Accordingly, applicant respectfully submits that the §112 Rejections to claims 1-7, as amended, are now overcome.

35 U.S.C. §103(a) Rejections

Claims 1-5 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Leskovar. Moreover, claims 1-7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Leskovar as applied to claims 1-5 and 7 above, and further in view of Housman. Applicant respectfully traverses the rejection made by the Examiner at least for the reasons set forth below:

Claims 1-6:

As set forth above, among other unique limitations, amended claim 1 recites a pharmaceutical composition that contains “*at least one compound having glutaminase activity*; and *at least one antineoplastic agent* selected from the group consisting of *platinum complexes* and *anthracyclines*” as active substances. (Emphasis added.)

According to the present invention, removal of glutamine by glutaminase active compounds deprives cancer cells of an important antioxidant which further contributes to their vulnerability to cytostatic agents. The combined pharmaceutical composition of cytostatic agents and glutaminase active compounds has synergistic effects in treatment of cancer. When the composition is administered to a patient, the glutamine level in blood of the patient is systemically reduced to weaken cancer cells, thereby enhancing the effectiveness of cytotoxic agents.

In contrast, and understood by applicant, Leskovar discloses a pharmaceutical composition for the treatment of cancer comprising a component A, eliminating suppressor-T-cells in a specific or non-specific way, and a component B, activating effector cells (Leskovar,

Abstract). The component A contains antibodies that are specific for a variety of cells. Elimination of suppressor cells is carried out using the antibodies (Leskovar, para. [0018]). Also, heterconjugates composed of the antibodies of the component A and a molecule that is toxic can be used for suppressor cells (Leskovar, para. [0021]). Essential component B, activating the effector cells, comprises lymphokines and monokines (Leskovar, paras. [0043] and [0044]). There are additional conjugates which may be useful in the composition such as immunoconjugates composed of target cell-recognizing antibodies and enzymes (asparaginase, glutaminase, etc) cleaving essential cell metabolites (Leskovar, paras. [0190]-[0194]). In other words, Leshovar discloses a drug having a component A and a component B for targeting with specific antibodies, the inventive composition of amended claim 1, however, comprises neither the component A nor the component B.

Furthermore, it is understood by applicant that Housman discloses a pharmaceutical composition that includes “at least one allele specific inhibitor targeting at least one but less than all allelic forms of a conditionally essential gene in a population, along with a pharmaceutically acceptable carrier or excipient.” (Housman, col. 5, lines 49-52.) In a preferred embodiment, the composition includes “at least one allele specific inhibitor and another antineoplastic agent, which need not be an allele specific inhibitor.” (Housman, col. 5, lines 60 and 61.)

Therefore, neither Leskovar nor Housman, taken alone or in combination, suggests or teaches a pharmaceutical composition that contains “*at least one compound having glutaminase activity*; and *at least one antineoplastic agent* selected from the group consisting of *platinum complexes* and *anthracyclines*,” according to amended claim 1 of the present invention.

For at least the foregoing reasons, independent claim 1, as amended, is patentable under 35 U.S.C. § 103(a) over the cited references.

Accordingly, amended claims 2-6, which depend from now allowable amended claim 1, are patentable at least for this reason.

Claim 7:

Claim 7, as amended, among other unique limitations, discloses a process for producing the pharmaceutical composition as claimed in amended claim 1, and depends from amended claim 1.

Referring to and incorporating herewith the above reasons why amended claim 1 is patentable, amended claim 7 is also patentable over the cited references at least because it depends from now allowable amended claim 1.

New Claim 10:

New claim 10 depends from now allowable amended claim 7, and therefore should be also patentable at least for this reason.

Any amendments to the claims not specifically referred to herein as being included for the purpose of distinguishing the claims from cited references are included for the purpose of clarification, consistence and/or grammatical correction only.


This application is believed to be in condition for allowance, and such action is earnestly solicited.

If the Examiner has any questions concerning this Response or the Application in general, the Examiner is requested to contact the undersigned at the number listed below.

Respectfully submitted,

MORRIS, MANNING & MARTIN, LLP

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Tim Tingkang Xia
Attorney for the Applicant on the Record
Reg. No.: 45,242

Morris, Manning & Martin, LLP
3343 Peachtree Road, N.E.
Atlanta, Georgia 30326-1044
Telephone: 404.233.7000
Customer No. 24728